Fresenius Bloodlines with HemoSafe Patient Connector
"Special" 510(k) Premarket Notification

JUL 28 2000

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9082
Contact Person:	Arthur Eilinsfeld, Regulatory Affairs Manager
Date of Preparation:	19 June, 2000

B. Device Name:

Trade Name:	Fresenius HemoSafe Patient Connector
Common/Usual Name:	Accessory to Set, Tubing, Blood, with and without Anti-regurgitation Valve
Classification Name:	Set, Tubing, Blood, with and without Anti-regurgitation Valve

C. Predicate Device Name:

The predicate devices for the Fresenius Bloodlines with Patient Connector Clip are the Fresenius Bloodlines cleared under the following premarket notifications:

- #K962081 (11/01/96);
- #K001107 (pending);
- #K000451 (05/09/00);
- #K971313 (10/27/97);
- #K971687 (07/29/97);
- #K920797 (09/21/92).

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D. Device Description/Indications for Use:

The Fresenius HemoSafe Patient Connector is intended to decrease the possibility of a compete disconnection of the bloodline and catheter during the dialysis treatment. It is not intended to replace the function of luer connectors and the rotating collar of bloodline patient connector.

There is no change to the bloodline Indications for Use as a result of the addition of the HemoSafe Patient Connector.

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Bloodlines with HemoSafe Patient Connector are devices pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the HemoSafe Patient Connector is as follows:

Intended Use

The Fresenius HemoSafe Patient Connector is intended to decrease the possibility of a compete disconnection of the bloodline and catheter during the dialysis treatment. It is not intended to replace the function of luer connectors and the rotating collar of bloodline patient connector.

The intended use of the Fresenius Bloodlines has not changed from that listed in their respective premarket notifications as a result of the addition of the HemoSafe Patient Connector.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The addition of the HemoSafe Patient Connector as an accessory to the Fresenius Bloodlines raises no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the HemoSafe Patient Connector and demonstrates that the Fresenius Bloodlines utilizing the HemoSafe Patient Connector are substantially equivalent to the standard Fresenius Bloodlines.

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F. Safety Summary

The following verification activities were performed to assess the impact of the addition of the HemoSafe Patient Connector to the various bloodline / central line catheter connections covered in this premarket notification:

- Immersion;
- Simulated use;
- Efficacy;
- Packaging.

The results of this testing indicate that the Fresenius HemoSafe Patient Connector is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains Directions for Use, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2000

Mr. Arthur Eilinsfeld
Regulatory Affairs Manager
Fresenius Medical Care North America
Two Ledgemont Center
95 Hayden Avenue
Lexington, MA 02420

Re: K001873
Fresenius Hemosafe™ Patient Connector
Dated: June 19, 2000
Received: June 20, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJK

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius HemoSafe Patient Connector

Indications for Use:

The Fresenius HemoSafe Patient Connector is intended to decrease the possibility of a compete disconnection of the bloodline and catheter during the dialysis treatment. It is not intended to replace the function of luer connectors and the rotating collar of bloodline patient connector.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K001873

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)